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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, RUTH S	
ART UNIT	**PAPER NUMBER**
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,984	MANDRUSOV ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-14,32 and 38-55* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3-14,32 and 38-55* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 7, "the distal opening of the delivery lumen" lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-14,38-43, 46-48,51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al (6,602,241) in view of Flaherty et al (6,726,677) or Lax et al (5,672,153). Makower et al disclose a method of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site using a

phased array transducer. The imaging is used to guide the positioning and rotational orientation of the catheter within the vasculature to ensure proper placement of the penetrator to the target site. Makower discloses that the desired treatment site can include a periadventital area outside but close to the vessel wall (col 3, lines 1-9). Imaging 360 degrees about the vessel wall using a phased array positioned at the catheter tip will inherently include imaging a thickness of at least a portion of the vessel wall as evidenced by Jenkins (5,109,859), see figures 1A,B. The image includes a penetrator path indication that indicates the path that will be followed by the penetrator when it is advanced to the target site. The path indication is interpreted as identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The treatment agent can include a sustained release composition in a carrier (col 16, lines 50-67, col 17, lines 1-5). The treatment agent can include an inflammation-inducing agent directed to a specific binding site to stimulate angiogenesis (col 1-2). The device is advanced through the vessel wall to an extravascular treatment site and therefore would provide the treatment site as set forth in claims 5,6. Makower et al fails to disclose the delivery device comprises a balloon and a delivery lumen coupled to the balloon where the balloon is used to urge the delivery lumen in a direction of the wall of the blood vessel. Flaherty et al and Lax et al each disclose the use of a balloon to urge a portion of a medical device toward the wall of a vessel in the body in order to improve its positioning at a desired location. It would have been obvious to one skilled in the art to have modified Makower et al such that it includes a balloon which is inflated to cause the delivery lumen to move in a direction of the wall of the vessel. The advantage of such is to improve the chances of properly positioning the needle in its desired location. The use of Makower et al would appear to include treatment sites as set forth in claims 7,8 however, the use of the device for any known treatment site in the body would have been obvious to one skilled in the art given the disclosed agents provided by Makower et al. With respect to claim 10, in the absence of any showing of criticality, the specific size of the carrier used would have been an obvious design choice of known equivalents in the art. With respect to claims 11-13,

41-43,46, 47,51,52, in the absence of any showing of criticality, the specific type of drug delivered would have been an obvious selection of known drugs and their uses based upon the desired patient treatment. The catheter includes a flexible needle device for both penetrating the vessel wall and for delivering treatment material. The device is considered be a "ribbon member deflector" which deflects the tip of the needle.

Claims 4,32,54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Flaherty et al or Lax et al as applied to claims 1,38 above, and further in view of Selmon et al (6,514,217). Makower et al as modified by Flaherty et al or Lax et al disclose the invention as discussed above but fail to disclose the use of optical imaging such as OCT. Makower et al disclose that other types of imaging devices can be used instead of ultrasound. The use of both ultrasound and OCT are well known in the art for imaging blood vessels as seen for example in Selmon et al. It would have been obvious to one skilled in the art to have further modified Makower et al such that the imaging modality used is OCT. Such a modification merely involves the substitution of one known type of imaging modality for another.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Flaherty et al or Lax et al as applied to claim 9 above, and further in view of Segal (2002/0131974). Makower et al as modified disclose the invention as discussed above but fails to specifically disclose the use of an opsonin-inhibitor. As disclosed in Segal the use of an opsonin-inhibitor is known in order to modulate the response to carriers put into a subject for treatment purposes. It would have been obvious to one skilled in the art to have further modified Makower et al such that the carrier includes an opsonin-inhibitor as is a well known expedient in the art of drug delivery.

Claims 12, 13,41-43,47,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Flaherty et al or Lax et al as applied to claims 1,38 above, and further in view of Slepian et al (5,749,915). Makower et al as modified disclose the invention as discussed above but fails to specifically disclose the agents set forth. The use of materials such as polycaprolactone and polyurethane for treatments involving blood vessels are known as taught by Slepian et al and the use of such known materials would have been obvious. The materials can be incorporated into carriers for delivery such as nanoparticles or liposomes and can include other particles such as metallic particles. The materials can be inflammation inducing and are heated when introduced into the body. It would have been obvious to one skilled in the art to have modified Makower et al such that materials, such as polycaprolactone and polyurethane in carriers such as metallic particles are used to further treat the vessels as is a well known expedient in the art.

Claims 44-45,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Flaherty et al or Lax et al as applied to claims 1,38 above, and further in view of Yock (5,676,151) or Ouchi (6,338,717). Makower et al as modified disclose the invention as discussed above but fails to specifically disclose the use of a balloon through which the imaging occurs. It is a well known expedient in the art to provide a balloon at the end of a device paced in the body in order to the device to be fixed at a desired location. Examples of medical devices which include a balloon at the tip of the device and an imaging means which images through a transparent material of the balloon is shown in Yock and Ouchi. It would have been obvious to one skilled in the art to have further modified Makower et al such that the catheter includes a balloon through which the imaging occurs as such is a well known expedient for positioning a catheter in the body for diagnosis or treatment.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Flaherty et al or Lax et al as applied to claim 1 above, and further in view of Myers et al (5,725,551). Makower et al as modified disclose a method

of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site. The image includes a penetrator path indication that indicates the path that will be followed by the penetrator when it is advanced to the target site. The path indication is interpreted as identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The imaging transducer is located in a lumen of the catheter and can include an ultrasound imaging device. Makower et al fail to disclose measuring the thickness of the vessel wall imaged. It is well known in the art that ultrasound can be used to determine vessel wall thickness. An example of such is seen in Myers et al. It would have been obvious to one skilled in the art to have used the ultrasound imaging device of Makower et al to further measure the thickness of the vessel wall and use the thickness measurement in addition to the images to further ascertain the path to the treatment site.

Response to Arguments

Applicant's arguments with respect to claims 1,3-14,32,38-55 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is (571)272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS